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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/697,142

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Charles P. Semba

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Goodwin Procter LLP

Attn: Patent Administrator

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EXAMINER

UNDERDAHL, THANE E

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

02/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/697,142	Applicant(s) SEMBA, CHARLES P.	
	Examiner THANE UNDERDAHL	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/6/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This Office Action is in response to the Applicant's reply received 11/6/08. Claims 7-14 are pending. No claims are withdrawn. Claims 1-6 are cancelled. Claim 7 has been amended. Claims 10-14 are new.

Response to Applicant's Arguments

Response to Applicant's Arguments— 35 U.S.C § 112

In the response submitted by the Applicant the 35 U.S.C § 112 rejection of claim 1-9 is withdrawn in light of the Applicant's cancellation of claims 1-6 and argument. However it is noted that the claim language of "time sufficient to remove fibrin-bound blood clots obstructing the flow of fluids within the catheter" is broad. Indeed this time would depend on many variables including the size of the clot or the size of the catheter. For example, catheter of large size and occluded by an extremely small clot would take very little time for removal. Also the common use of the word "obstructing" does not limit that the fluid in the catheter is completely sealed or all fluid flow is halted. Indeed synonyms for obstruct include impede or hinder which do not limit that the flow of fluid is completely halted (see www.merriam-webster.com/dictionary/obstruct).

Furthermore the claims are to a composition and limitations stating "a time sufficient to remove fibrin-bound blood clots obstructing the flow of fluids within the catheter" is an intended use and intended result (M.P.E.P. § 2111.02). Compositions are defined by their components. Therefore as the Applicant pointed out, the claim is to

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an "indwelling catheter containing a solution comprising 0.01 to 0.05 mg/mL of tenecteplase in sterile water for injection or bacteriostatic water for injection and normal saline". Therefore art reading on a catheter with this solution will have all the physical characteristics to achieve the intended result of removing the clot obstructing the flow of fluids within the catheter since the physical makeup of the solutions taught in the art are the same.

Claim Objections

Claim 14 is objected to since the range of about 0.01 to 0.15 mg/mL does not further limit the range of independent claim 7 which is smaller at about 0.01 to 0.05 mg/mL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed range of Tenecteplase at a concentration of about 0.01 to 0.15 mg/mL does not have support in the as filed specification. Indeed page 15 of the specification does include ranges of Tenecteplase

such as 0.01 to 0.04 mg/mL or even 0.01 to 0.015 mg/mL but not as high as 0.15 mg/mL of Tenecteplase.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of remaining claims 7-9 over Sandbaek et al. (Blood Coagulation and Fibrinolysis, 1999) as supported by DrugBank (def "Tenecteplase") in view of Graney et al. (Australian Patent AU-B-42810, published 1992) were considered but not found persuasive.

The Applicant argues that Sandbaek does not teach "An indwelling catheter containing...tenecteplase...for a time sufficient to remove fibrin-bound blood clots obstructing the flow of fluids within the catheter" since Sandbaek teach a method "to dissolve blood clots in the arteries" and the their enzyme solution is "not allowed to stay in the catheter for *any* extended period of time, since the catheter simply serves as a conduit to deliver the drug to the clot in an artery" (Applicant Response, pg 4, 1st full paragraph). However as mentioned above the claims are to a composition and since compositions are defined by their physical components any art teaching these components will read on the claim. The limitations such "for a time sufficient to remove... blood clots obstructing the flow of fluids within the catheter" are an intended use and intended result and do not further limit the structural characteristics of the composition and are not given patentable weight.

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Indeed since Sandbaek et al. does teach a solution containing an art-recognized equivalent for tenecteplase and this solution does reside in a catheter for some period of time, they teach the limitations of claim 7 and dependant claims 8-14.

The Applicant argues that the alteplase taught by Sandbaek et al. and Graney are not art recognized equivalents for the same purpose since alteplase has a lower potency and would not be used to remove blood clots from an indwelling catheter in the concentration ranges recited in the claims. This argument is merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See M.P.E.P. § 2129 and § 2144.03 for a discussion of admissions as prior art. Counsel's arguments cannot take the place of objective evidence. *In re Schulze*, 145 USPQ 716 (CCPA 1965); *In re Cole*, 140 USPQ 230 (CCPA 1964); and especially *In re Langer*, 183 USPQ 288 (CCPA 1974). See M.P.E.P. § 716.01(c) for examples of attorney statements that are not evidence and that must be supported by an appropriate affidavit or declaration.

Therefor the rejection stands and is repeated below with alterations to include the new claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandbaek et al. (Blood Coagulation and Fibrinolysis, 1999) as supported by DrugBank (def "Tenecteplase") in view of Graney et al. (Australian Patent AU-B-42810, published 1992).

These claims are drawn to a composition containing about 0.01 to 0.05 mg/mL of Tenecteplase in sterile water or bacteriostatic water and normal saline comprised in an indwelling catheter. Claims 10-13 further limit the range of the highest concentration of Tenecteplase in solution to about 0.04 mg/mL, 0.03 mg/mL, 0.02 mg/mL, 0.15 respectively. Claim 14 further limits the Tenecteplase be in sterile water.

Sandbaek et al. teach a concentration of Alteplase in saline at a final concentration of 0.02 mg/mL and is administered by an indwelling catheter (page 88, col 1, "Intra-arterial thrombolysis") to dissolve fibrin bound blood clots that are 2-30 days old (page 87 col 2 to page 88 col 1). Alteplase is an art recognized equivalent for the same purpose as Tenecteplase (M.P.E.P. § 2144.06) since both have the same activity to dissolve blood clots (see OA mailed 8/24/07 page 2 to 3).

Also while Sandbaek et al. teach their composition in saline, they do not provide the details on the composition of the saline and thus do not anticipate the limitation of sterile water for injection or bacteriostatic water for injection and normal saline. This is taught by Graney et al.

Graney et al. teach that Tenecteplase (called the synonym tPA or tissue plasminogen activator or Alteplase by Graney, page 7, lines 1-2) can be included in compositions where the solvent carrier is sterile water (page 7, line 8) or distilled water,

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Ringer's solution as well as saline and other conventional carriers (page 8, lines 19 and 20). Therefore Graney et al. teach that saline as well as sterile water for injection and other conventional pharmaceutical carriers can be used interchangeably to dissolve and administer Tenecteplase and are therefore art recognized equivalents for the same purpose and it would be obvious for one of ordinary skill in the art to substitute saline from sterile water for injection (M.P.E.P. § 2144.06).

Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 7-14 are not allowable.

No claims are currently allowed in this application.

Applicant's amendment adding new claims necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651